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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,510	06/02/2000	William G. Skelly	503775.008	7522

7590 07/14/2003

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/586,510	SKELLY, WILLIAM G.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 21-25* is/are pending in the application.

4a) Of the above claim(s) *8-12 and 21-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Applicant's election of the species equine respiratory complex in Paper no. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse. See MPEP section § 818.03(a)).

2. Claims 22,23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 12.

3. Applicant's election of the species EIPH and IgG in Paper no. 14 is acknowledged. Applicant has indicated in the Interview Summary of 5/15/203 that iv and intratracheal is the species to be elected versus the species referred to in Paper no. 14. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse. See MPEP section § 818.03(a)).

4. Claims 8-12,21-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Regarding claim 24, said claim lacks antecedent basis in claim 1 (disease caused by stress versus disease caused by shipping and handling) and is being treated as a separate species. Election was made without traverse in Paper No. 12.

5. Claims 1-7,13-15 are under consideration. Claims 16-20 have been cancelled.

RESPONSE TO APPLICANTS ARGUMENTS

6. The request for the deletion of an inventor in this nonprovisional application under 37 CFR 1.48(b) (filed 2/11/2003) is deficient because the statement required

under 37 CFR 1.48(b)(2) is not signed by a party set forth under 1.33(b) as per required.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-7,13-15 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "exercised induced pulmonary hemorrhage" or "respiratory disease complex resulting from shipment or crowding" or "upper respiratory infections accompanying stress" or "and/or combinations thereof" in claim 1. Applicant has indicated that said phrases find support in the specification, pages 9 and 10. However, said disclosure is limited to a disclosure of "bovine and/or porcine respiratory disease complex which often occurs in cattle and swine respectively when shipped or corralled for slaughter", EIPH in horses and "upper respiratory infections accompanying stress in horses". There is no disclosure in the specification as originally filed of the scope of the claimed inventions which does not include extra additional limitations underlined above. The absence of the aforementioned limitations enlarges the scope of the claimed invention such that it lacks support in the specification as originally filed. Also, there is no disclosure of the limitation "and/or combinations thereof" in the context recited in claim 1.

Regarding claim 2, while treatment of EIPH in horses is disclosed in the specification, treatment of EIPH per se is not disclosed in the specification as originally filed.

Regarding claims 3-5,13-15 said limitations in the original claims applied to a method of treating EIPH in horses. Treatment of the other diseases recited in claim 1 (or

EIPH in animals other than horses) is not disclosed in the specification as originally filed.

Regarding claim 6, there is no support in the specification as originally filed for the recitation of "and/or combinations thereof". The specification only discloses the combined administration as per original claim 7 (treating EIPH in horses) or as per the specification, page 11, first paragraph. In addition, the method of original claims 6/7 is limited to a method of treating EIPH in horses. There is no disclosure of the scope of the claimed invention wherein the administration is as per recited in claim 6/7 as applies to all of the diseases recited in claim 1.

There is no support in the specification as originally filed for the scope of the claimed inventions (eg. the claimed inventions constitute new matter).

9. Claims 1-7,13-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the claimed method of treating exercise induced pulmonary hemorrhage (EIPH) recited in claim 1. The specification does not disclose how to use the instant invention for treating EIPH in vivo. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification. Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed

invention without 'undue experimentation.' " Genentech, Inc. v. Novo Nordisk, A/S , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.

We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not

'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In In re Wands , we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd. , 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

The state of the art is such that is unpredictable in the absence of any evidence as to how the instant invention could be used for the treatment of EIPH. As per Wands factor (3), the specification provides no working examples indicating that the method of the instant invention can be used for the treatment of EIPH. Erickson et al. teach that while the cause of EIPH is unclear, it appears to involve stress failure of pulmonary

capillaries(see pages 53 and 54). There is no evidence of record to suggest that IgG administration would have any effect on stress failure of pulmonary capillaries. Thus, it would be unpredictable as to whether IgG could be used to treat EIPH because there is no evidence of record to establish that IgG has any effect on stress failure of pulmonary capillaries. Thus, as per Wands factors (5) and (7), there is a high degree of unpredictability in the art and the prior art does not disclose evidence indicating that IgG can be used to treat EIPH. Furthermore, to the extent that the claims encompass Ig administration other than Ig, Hillidge et al. teach that IgE levels are actually increased in horses suffering from EIPH (see abstract). Based on the aforementioned undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. Undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification and the prior art alone. See In re Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404.

Regarding applicants comments, the Sheldon II declaration does not address EIPH and is therefore not germane to the instant rejection. Regarding the Erickson II declaration, additional information is required in order to fully evaluate the comments made in said declaration. Regarding point 8, a description of what specific Ig composition was used (a variety of different compositions are referred to in the "background section" of the instant application), how it was administered, when it was administered, what were the nature of controls used and what dosages were used is needed in order to determine the relevance of the experiments referred to in comparison to the disclosure of the specification and the scope of the claimed invention.

10. The claimed inventions are not disclosed in parent application 08/349010 and therefore regarding the application of prior art, priority is extended only to parent application 08/685052.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 1,5,6,13-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Ragland et al.

Upper respiratory infections accompanying stress is currently recited in claim 1.

The disease treated in Ragland et al. appears to be an upper respiratory disease associated with stress. Ragland et al. teach intravenous treatment of said horses with 20 ml of Seramune an equine immunoglobulin(see column 1, page 2). Said immunoglobulin would contain IgGt because it is the predominant Ig found in horses. IgGt is a equine form of IgG. Presumably the Seramune would contain at least trace amounts of complement because complement is a blood protein and the Ig preparation is prepared from treated blood. Seramune is a polyclonal immunoglobulin preparation

(eg. it would contain antibodies with the various specificities found in the horse(s) from which it was obtained).

Regarding the Skelly declaration, it appears that the Skelly declaration is an attempt to overcome the Ragland et al. reference using a Katz type 1.132 declaration. However, in view of the fact that Skelly is not an author of said publication, such a type of declaration cannot be used to overcome the rejection. In addition, the Skelly declaration appears to state that he is a co-author of the publication (see section 5) when he is not listed on the publication. Furthermore, the Skelly declaration section 4, lists a variety of individuals who apparently had knowledge of the claimed invention who are not inventors of the instant application without clearly indicating who communicated with the authors of the Ragland et al. publication (eg. see section 4, line three) and how they had knowledge of the claimed invention if they were not inventors.

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at the RightFax AF number 703-872-9307.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1200 1600

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644